

REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment is respectfully requested. Claims 1-14 are pending, with 1 and 8 being the independent claims. Claims 1-3, 6-9, and 11 have been amended and are directed to the elected species of FIG. 4C. Support for the amendment of the claims can be found throughout the specification, and particularly in paragraphs [0016], and [0058]-[0062] and FIG. 4C. Claims 13 and 14 have been added. The foregoing amendment does not introduce any new matter and its entry is respectfully requested.

35 U.S.C. §103(a) Rejections

Claim 1 is rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,004,310 to Bardsley et al. in view of U.S. Patent No. 4,988,356 to Crittenden et al. The Examiner states that Bardsley et al. discloses a catheter having a guidewire lumen, an arcuate shaped inflation lumen, and “a support strip 135 embedded within a wall of the shaft.” Office Action p. 3. The Examiner relies on Crittenden et al. for a longitudinal cut extending radially from an outer surface of the shaft to the guidewire lumen. The Examiner states that it would have been obvious “to modify the device of Bardsley with a longitudinal cut, as taught by Crittenden, in order to provide a means for inserting and removing an object, such as a guide wire.” *Id.*

Applicants traverse the Examiner’s rejection of claim 1, as Bardsley et al. does not teach a support strip as claimed. As an initial matter, Bardsley et al. teaches a **tubular** support member (135, 225, 330, 535, 635) for maintaining the circular cross-section of the guidewire lumen to prevent distortion and possible closing-off or kinking of the guidewire lumen during operation. *See* Bardsley et al., col. 1, lines 50-53; col. 2, lines 13-31; col. 5, lines 7-11; col. 6, lines 14-20; col. 6, line 66- col. 7, line 4; col. 7, lines 29-33; and col. 8, lines 59-65; FIGS. 2-5, 7 and 8. The support member (135) is necessarily concentrically disposed about the inner member (130) to provide maximum lumen integrity. *See* Bardsley et al., col. 6, lines 56-63; FIG. 2. In contrast, the support strip of claim 1, as amended and as shown in FIG. 4C, is recited as “plank-like” to clarify its structure as a nontubular strip of material that is radially disposed within a wall of the shaft between the guidewire lumen and an outer surface, as such the support strip is clearly recited to extend along only one side of the guidewire lumen and is also recited to be proximate the longitudinal cut. The structure and position of the plank-like support strip of claim 1 is not taught or suggested by the tubular support member of Bardsley et al.

In addition, Applicants contend that the proposed modification of Bardsley et al. in view of Crittenden et al. would make the multilumen catheter shaft of Bardsley et al. unfit for its intended purpose such that one of ordinary skill in the art would not find it obvious to make the proposed modification. Bardsley et al. teaches fortifying the guidewire lumen by encircling or surrounding the lumen with a tubular support member (135), which ensures the integrity of the cross-sectional shape of the lumen and prevents the lumen walls from being distorted or deflected against the guidewire during an interventional procedure. *See* Bardsley et al., col. 6, lines 14-20; col. 6, line 56-col. 7, line 2. The Examiner's suggested addition of a longitudinal cut through the shaft wall of the catheter of Bardsley et al. to the guidewire lumen (110) would result in the tubular support member (135) being cut too, thereby eliminating or drastically diminishing any reinforcement or support benefit that support member (135) was to provide the lumen. Thus, one of ordinary skill in the art would not find it obvious to modify the catheter of Bardsley et al. with a longitudinal cut as disclosed in Crittenden et al. For the foregoing reasons, Applicants contend that claim 1 is patentable over the disclosure of both the Bardsley et al. and Crittenden patents, taken alone or in combination.

Claims 2-7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bardsley et al. in view of Crittenden et al. and further in view of U.S. Patent No. 6,059,769 Lunn et al. The Examiner states that Bardsley et al. and Crittenden et al. disclose the device substantially as claimed but do not disclose a reinforcement member and joint member as described in claims 2-7. The Examiner relies on Lunn et al. as disclosing "reinforcement 32, [and] joint members 52 fixed within a groove in the shaft." Office Action p. 4.

As discussed above with reference to independent claim 1, Bardsley et al. and Crittenden et al. do not disclose or suggest a plank-like support strip as recited nor is the addition of a longitudinal cut to the device of Bardsley et al. obvious to one of ordinary skill in the art. Lunn et al. does not make-up for the deficiencies in the primary references. Similar to Bardsley et al., Lunn et al. teaches a **tubular** reinforcing section (32) that surrounds guidewire lumen (36). Lunn et al. col. 3, lines 55-60; FIG. 2. Lunn et al. does not teach or suggest a plank-like support strip as recited in claim 1. As such, independent claim 1 is patentable over Bardsley et al., Crittenden et al. and Lunn et al. alone or in combination. Claims 2-7 depend from and add further features to independent claim 1 and are patentable for that reason alone. However while it is not necessary to address the Examiner's rejection of the dependent claims at this time, Applicants reserve the right to support their patentability, when necessary.

Of note however is that Bardsley et al and Lunn et al, each disclose the **same type of tubular reinforcement** of a lumen and that together they do not disclose a plank-like support strip **and** a curved reinforcement member, as currently recited in amended claim 2. Further, the joint member claimed in amended claim 3 is recited as being disposed at a **circumferential location between** the support strip and the curved reinforcement member, which is not present in any combination of the cited references. Applicants note that the amendments of claims 2, 3, 6 and 7 were to clarify the subject matter thereof, and the Examiner is requested to independently re-consider each.

Claims 8-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bardsley et al. in view of Crittenden et al. and further in view of Lunn et al. The Examiner states that Bardsley et al. discloses a catheter having a guidewire lumen, an arcuate shaped inflation lumen, and “support strips 135 embedded within a wall of the shaft.” Office Action p. 4. The Examiner relies on Crittenden for a longitudinal cut extending radially from an outer surface of the shaft to the guidewire lumen. The Examiner states that it would have been obvious “to modify the device of Bardsley with a longitudinal cut, as taught by Crittenden, in order to provide a means for inserting and removing an object, such as a guide wire.” *Id.* at 5. The Examiner relies on Lunn et al. as disclosing “reinforcement 32, [and] joint members 52 fixed within a groove in the shaft.” *Id.* The Examiner states that it would be obvious to modify the device of Bardsley et al. in view of Crittenden et al. “with reinforcements and a *joint members longitudinal cut*, as taught by Lunn, in order to provide improve[d] flexibility of the distal end” of the catheter and to prevent kinking. *Id.* (emphasis added).¹

Independent claim 8, as amended, recites a shaft having a pair of plate-like support strips embedded in a wall of the shaft that are radially disposed between the guidewire lumen and an outer surface of the shaft portion and disposed on opposing sides of the longitudinal cut. As discussed above, Bardsley et al. discloses only a tubular support member (for example item 135) that encircles a lumen to provide support thereto, and neither Crittenden et al. or Lunn et al. discloses such a pair of support strips. As such, at least this element is entirely missing from the combination of Bardsley et al., Crittenden et al., and Lunn et al. Further as discussed above with reference to independent claim 1, one of ordinary skill in the art would not find it obvious to modify the catheter of Bardsley et al. with a longitudinal cut as disclosed in Crittenden et al., as

such a longitudinal cut would destroy the functionality of the support member taught by Bardsley et al. For at least this reason, claim 8 is patentable over the combination of Bardsley et al., Crittenden et al., and Lunn et al.

In addition independent claim 8, as amended, recites a curved reinforcement member entirely embedded in the shaft wall and radially disposed between the inflation lumen and the outer surface of the shaft portion. In contrast, each of Bardsley et al and Lunn et al disclose the **same type of tubular reinforcement** of a lumen and neither teaches or suggests a curved reinforcement member entirely embedded in a wall of the shaft radially outward of the inflation lumen. Finally, claim 8 also recites that a pair of joint members are disposed at **different circumferential locations between** the support strip and the curved reinforcement member, which is not present in any combination of the cited references. As such, independent claim 8 is patentable over Bardsley et al, Crittenden et al. and Lunn et al. alone or in combination. Claims 9-12 depend from and add further features to independent claim 8 and are patentable for that reason alone. However while it is not necessary to address the Examiner's rejection of the dependent claims at this time, Applicants reserve the right to support their patentability, when necessary.

New Claims

New claims 13 and 14 depend from and add further features to independent claim 8 and are patentable over Bardsley et al, Crittenden et al. and Lunn et al. alone or in combination for that reason alone.

¹ Applicants are not sure what the Examiner meant by the emphasized language, as the pair of recited joint members in claim 8 do not have a longitudinal cut.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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